April 26, 2022

The Honorable Micky Tripathi
National Coordinator for Health IT
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C St SW
Washington, DC 20201

Re: United States Core Data for Interoperability Draft Version 3

Fresenius Medical Care North America (FMCNA) welcomes the opportunity to comment on the draft version 3 of the United States Core Data for Interoperability (USCDI V3). FMCNA is the largest provider of services and supplier of products in the country for patients with end stage renal disease (ESRD) undergoing dialysis. We applaud efforts by the Office of the National Coordinator (ONC) to engage in meaningful dialogue with stakeholders to expand the USCDI to improve information exchange and advance health equity. Many of our patients belong to historically underserved communities and have significant care needs due to their chronic illness. We believe the addition of ESRD-specific data elements to the USCDI, in V3 or future versions, would be a critical step toward improving outcomes and reducing disparities for patients with kidney disease.

Better exchange of dialysis patient data between providers involved in their care could reduce hospital readmissions, a key priority for both the Centers for Medicare and Medicaid Services (CMS) and FMCNA. Almost 34 percent of patients with ESRD are re-hospitalized within 30 days, which is nearly twice the rate in the general Medicare population.[1] There is a clear opportunity to reduce readmissions. Once a patient is discharged by the hospital, critical information specific to their dialysis prescription must be exchanged, and in many cases, this is not happening. Inclusion of health data classes and data elements to the USCDI that cover the dialysis treatment would be an important step toward facilitating smooth information transfer.

Currently, when a patient is discharged from the hospital, critical dialysis treatment information may be missing from discharge documents, potentially delaying necessary treatment and compromising patient safety. Certain dialysis parameters are necessary for the dialysis clinician to know when a patient returns after a hospitalization because certain elements of treatment may be altered during the hospital stay. The dialysis clinic staff will have difficulty dialyzing the patient without access to this data. Incoming continuity of care documents (CCD) from hospitals that dialyzed a patient in the acute setting often do not contain critical data elements that could be of lifesaving importance, such as current dialysis treatment prescription, dialysis medications, last dialysis treatment related information (pre and post dialysis treatment vitals, weights, dialysate concentration) and lab results.

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[1] United States Renal Data System. 2020 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* End Stage Renal Disease: Chapter 4. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020. https://adr.usrds.org/2020/end-stage-renal-disease/4-hospitalization#:~:text=Rates%20of%20hospital%20readmission%20within,not%20rehospitalized%20and%20died%2C%20respectively

Fresenius Medical Care North America

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Dialysis providers who participate in Health Information Exchanges (HIEs) use elements in the ESRD Implementation Guidelines on their outgoing CCD documents. We have developed our own renal-specific CCD to share with HIE participating providers containing common data elements imperative to dialysis care. However, often times, hospitals that provide dialysis treatments in the acute setting do not contain any of those critical data elements in their outgoing CCD documents. In many cases, the dialysis nurse or the nephrologist will have to call the hospital and try to obtain dialysis specific information before the patient can be dialyzed, delaying lifesaving care and increasing likelihood of a readmission.

To facilitate seamless transitions of care and reduce rehospitalizations, we believe updates to the USCDI guidelines should incorporate data elements specific to the dialysis treatment. We recommend the following data classes and data elements, which impact patient safety, should be incorporated in the USCDI starting with Version 3 and in future updates:

Data Class: Dialysis Treatment Prescription

Data Elements:

- Dialysis treatment time
- Dialysate (particularly potassium concentration)
- Dialysate flow rate
- Blood flow rate
- Vascular access
- Heparin dose
- Last treatment vital signs

- Intradialytic medications and dose
- Post treatment weight
- Most recent lab results prior to discharge
- Antibiotics administered during hospitalization
- Positive blood cultures drawn within 24 hours of hospital admission
- Transplantation referral and waitlisting data

Beyond hospital readmissions, common dialysis data elements would benefit other aspects of dialysis patient care. Many providers are involved in dialysis patient care including nephrologists, transplant centers, vascular access surgeons, and primary care clinicians. Patient information exchange among all care partners is critical. Furthermore, CMS models to improve care for Medicare beneficiaries with ESRD through coordinated care models require extensive semantic interoperability. Expanding the USCDI V3 specifications to include key renal data elements would directly and positively impact these important programs.

We serve a vulnerable population and see a great need to share information electronically between common care providers to give the best care possible based on the longitudinal patient record. Incorporating the dialysis data elements mentioned above into the USCDI would significantly improve continuity of care, patient safety and potentially prevent hospital admissions and readmissions. FMCNA appreciates having the opportunity to provide comment. We look forward to working with ONC to address the recommendations we have made in this letter.

Sincerely,

Dinesh Chatoth
Associate Chief Medical Officer, Fresenius Kidney Care

Statement of Support: eHealth Exchange

eHealth Exchange, the nation's largest Health Information Network, enthusiastically supports Fresenius Kidney Care's suggestions to include critical data elements for patients with End Stage Renal Disease (ESRD) in the United States Core Data for Interoperability (USCDI) Version 3 or future Version. If enacted, I am confident Fresenius' requests would dramatically improve clinical outcomes, reduce health disparities, improve care coordination, and decrease expenditures for these patients. Hospitals, nephrologists, and dialysis providers currently have very little visibility into critical dialysis treatment related data elements that affect patent safety during transitions of care. While we have already made substantial progress in data exchange, there are still a few critical fields that can greatly contribute to optimal outcomes in patients with ESRD.

Sincerely,

Jay Nakashima

Jay Nakashima

Executive Director, eHealth Exchange